REMARKS

Claims 1-3 have been amended. Claims 4-13 have been added. Accordingly, claims 1-13 are currently pending in the above-identified application.

35 U.S.C. §103(a)

Claims 1-3 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Sakagami (U.S. Patent No. 4,785,407) in view of Kopf-Sill (U.S. Patent No. 5,590,052) or Ginsberg (U.S. Patent No. 4,276,051). The rejection is traversed in view of the foregoing amendments and for the following reasons.

In order to prevent the occurrence of errors of determination due to cross-contamination occurring among the reagents and the occurrence of errors of determination due to generation of new contamination by variation of the state of the automatic chemical analyzer, the analyzer is provided with functions to set the determination conditions for judging the presence or absence of the cross-contamination, to make judgment of the combination of reagents involving the cross-contamination and to memorize the results of the judgments.

That is, the analyzer makes judgment on the presence or absence of the-cross-contamination for combinations of the reagents and compares the result with those of previous judgments. When the comparison produces results that differ by more than a certain degree, the user is notified. Without such notification, the user may not be able to determine that such new contamination exists.

In particular, such new contamination may be caused by a malfunction in the analyzer, such as a malfunction in the pipetting probe washing mechanism. It is known to those having ordinary skill in the art that a certain amount of cross-contamination occurs when multiple reagents are used in an analyzer. However, automatic analyzers of the prior art do not permit a user to determine cross-contamination errors and whether new contamination is causing errors due to variation of the state of the apparatus, as in the present invention. Such a change in the state of the apparatus may be caused by a malfunction of a washing mechanism, for example, and in the prior art a special testing procedure must be performed to determine if the washing mechanism is malfunctioning, which leads to inefficiency.

That is, it is possible to determine whether a washing apparatus is functioning correctly or not, however the procedure for making this determination generally requires pipetting a particular reagent not ordinarily used for analyses of the samples in the operations normally performed by the analyzer. For example, a particular reagent, such as a phosphate buffer, can be pipetted with a reagent pipetting probe, followed by washing the probe. Then, the amount of contamination of the phosphate buffer with another reagent can be determined in order to check the performance of the washing apparatus. In this example, since phosphate buffer is not commonly used in the analyses of patient samples, the operation to determine whether or not the probe washing mechanism is performing adequately must be determined in a separate procedure that slows down or degrades the efficiency of the analyzer.

On the other hand, the present invention is directed to preventing the occurrence of errors of determination due to generation of new contamination (and to the prevention of errors of determination occurring due to cross-contamination) by variation of the state of the apparatus, for example by malfunction of the washing apparatus for the reagent pipetting

probe. That is, the analyzer of the present invention performs the ordinary course of analysis of samples while at the same time determining whether new contamination has been generated by comparing the result of judgment on the presence or absence of cross-contamination for combinations of the reagents with those of the previous judgments. Accordingly, the claimed combination of the invention set forth in claims 1-13 is not rendered obvious by Sakagami in view of Kopf-Sill or Ginsberg.

In particular, Sakagami is relied upon for disclosing an automatic chemical analyzer using cuvettes, wherein after a predetermined maximum number of times that a cuvette is used or when a certain degree of deterioration is detected, the cuvette is removed and replaced with a new cuvette. An output signal of a colorimeter 26 is used to determine the degree of deterioration by comparing the output signal with a threshold level and determining that deterioration has occurred when the threshold level has been exceeded. In Sakagami, there is no comparison between previous and current measurements in the determining of the condition of contamination of the cuvette, as stated in the Office Action.

Kopf-Sill discloses a blood analyzer that includes determining the degradation of a reagent and a cuvette by comparing a currently measured value with a predetermined absorbance limit of contamination. When the measured value exceeds a limit, a warning is produced. Neither Sakagami or Kopf-Sill discloses judging the presence or absence of contamination and memorizing the result of the judgment. Further, neither describes comparing a currently determined judgment result with a previous judgment result to judge whether a state of the apparatus has changed, as claimed by Applicants.

The newly cited reference to Ginsberg et al discloses an automatic analyzer having a wash station including a wash stand 160 that has a plurality of probes 172 that are driven into the cuvettes. Wash fluid and vacuum are applied to the respective probes to wash, exhaust and dry the cuvettes. After this cycle, a blanking solution is injected through a probe into the cuvette and a measurement is taken with photometer 46 to determine if the cuvette has been washed. That is, the measured value of absorbance after washing is compared with that of the absorbance measured before the last test. This procedure is merely concerned with determining

whether the cuvette has been sufficiently washed, and not whether variation of the state of the apparatus has occurred that would affect judgment on the presence or absence of the cross-contamination for combinations of the reagents, as in the present invention. In Ginsberg, if the post washing measurement of the absorbance of the blanking solution is outside of the acceptable limits, then the cuvette is not involved in any further testing. Therefore, Ginsberg et al do not disclose the aspects of the claimed combination that are not mentioned in either Sakagami or Kopf-Sill. Accordingly, the combination of Sakagami and Kopf-Sill or Ginsberg et al does not render the invention as claimed obvious under 35 U.S.C. §103(a) and the rejection should be withdrawn.

Conclusion

In view of the foregoing amendments and remarks, Applicants contend that the above-identified application is now in condition for allowance. Accordingly, reconsideration and reexamination are respectfully requested.

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